IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTEGRA LIFESCIENCES CORP., INTEGRA LIFESCIENCES SALES LLC, CONFLUENT SURGICAL, INC., and INCEPT LLC,	:	
Plaintiffs,	:	
v.	:	C.A. No. 15-819-LPS-CJB
HYPERBRANCH MEDICAL TECHNOLOGY, INC.,	:	
Defendant.	:	

MEMORANDUM ORDER

WHEREAS, Magistrate Judge Burke issued a 27-page Report and Recommendation ("Report") (D.I. 508), dated February 20, 2018, recommending the Court grant Defendant HyperBranch Medical Technology, Inc's ("Defendant" or "HyperBranch") motion for summary judgment of non-infringement of claims 1, 6, 12, and 17 of the '5705 patent (D.I. 393);

WHEREAS, on March 2, 2018, Plaintiffs Integra LifeSciences Corp., Integra LifeSciences Sales LLC, Confluent Surgical, Inc., and Incept LLC (collectively, "Plaintiffs" or "Integra") objected to the Report (D.I. 529) ("Objections" or "Objs.");

WHEREAS, on March 12, 2018, HyperBranch responded to Integra's Objections (D.I. 551) ("Response" or "Resp.");

WHEREAS, the Court has considered the parties' objections and responses *de novo*, *see St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., Ltd.*, 691 F. Supp. 2d 538, 541-42 (D. Del. 2010); 28 U.S.C. § 636(b)(l); Fed. R. Civ. P. 72(b);

NOW THEREFORE, IT IS HEREBY ORDERED that:

1. Plaintiffs' Objections (D.I. 529) are OVERRULED, Judge Burke's Report (D.I. 508) is ADOPTED, and Defendant's motion (D.I. 393)[1] is GRANTED.

2. Integra objects that the Report improperly construed the claim language at issue by reading in additional limitations not present in the Court's construction. (Objs. at 2-5) Alternatively, Integra contends the Report wrongly concluded there was no material issue of fact regarding whether amide linkages are biodegradable. (*Id.* at 10) The Court is not persuaded by either of Integra's contentions.

3. Integra primarily contends the Report wrongly interpreted the esters limitation of the claims. (Objs. at 2) Representative claim 1, with the esters limitation emphasized, recites:

> A method of making a biocompatible degradable hydrogel to treat a medical condition of a patient comprising:
>
> identifying a medical condition for treatment by use of a hydrogel formed in situ in a patient and fully degradable in a patient in less than about 180 days; and
>
> mixing a first precursor with a second precursor in situ in the patient to form the hydro gel for treatment of the medical condition,
>
> with the first biocompatible synthetic hydrophilic polymer precursor having a water solubility of at least 1 gram per 100 milliliters and comprising at least two electrophilic functional groups; and the second biocompatible synthetic hydrophilic polymer precursor comprising at least two nucleophilic amine functional groups; and
>
> wherein

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[1]The underlying Report, and accordingly this Order, solely addresses the portion of Defendant's motion (D.I. 393) related to summary judgment of non-infringement of claims 1, 6, 12, and 17 of the '5705 patent (*see* Report at 1 n.2).

(i) the first precursor is selected have only one or two chemically hydrolytically degradable ester bonds per every electrophilic functional group on the first precursor; and

(ii) the second precursor comprises at least three nucleophilic functional groups;

wherein ***the biodegradable groups of the hydrogel consist of the esters*** and the hydrogel as placed in situ in the patient is essentially fully degradable in a patient in less than about 180 days, and

wherein mixing the first and the second synthetic hydrophilic polymer precursors forms crosslinking covalent bonds that are reaction products of the electrophilic and the nucleophilic groups, wherein essentially every ester bond in the hydrogel is separated from other ester bonds in the hydrogel by at least three covalent bonds when the hydrogel is formed.

(Emphasis added)

4. In November 2017, the Court construed the esters limitation as "the hydrogel does not contain any biodegradable linkages other than ester linkages." (D.I. 379 at 8-10) In doing so, the Court specifically rejected Integra's argument that such a construction improperly excluded "all non-ester groups that may be biodegradable to even a small or insignificant extent and over a very long period of time beyond 180 days," finding that contention to be contrary to both the claim language and prosecution history. (*See id.*) Integra reiterates the same arguments here in objecting to the Report. The Court continues to find them unpersuasive.

5. Integra contends that the Report improperly provides a new construction of the esters limitation that "only an amide linkage that ***'never'*** breaks ***'at all'*** under any conditions in the human body without any time limit can be covered by the claims." (Objs. at 1) Under "[a] correct understanding," Integra contends, "the claims as a whole allow[] biodegradable esters to coexist with nonbiodegradable amide linkages in the hydrogel during the claimed degradation times for the hydrogel of 180 days or 90 days when the hydrogel is still in the patient." (*Id.*) Integra is correct that biodegradable esters may coexist with ***nonbiodegradable*** amide linkages in the hydrogel within the scope of the claims, but whether the amide linkages are biodegradable as construed by this Court is not dependent upon the time of degradation. Claim 1 requires the hydrogel be "fully degradable in a patient in less than about 180 days," but no such timing requirement is specifically tied to the linkages of the biodegradable groups. Moreover, Integra contends that "the applicants expressly limited the biodegradable groups of the hydrogel of claim 1 to esters, while expressly maintaining the presence of amide linkages in the very same hydrogel" (Objs. at 7), but this is inconsistent with the applicants' position during prosecution, in which they stated that "adding a polyanhydride [(a non-ester material)] places the precursor outside of the claims" (D.I. 232 Ex. 6 at HBMT0409344, HBMT0409377; D.I. 316 at 13-15). The Court agrees with the Report's conclusion that "the esters limitation places a hydrogel outside of the scope of the claims when it includes biodegradable groups other than ester linkages that are able to be degraded when used in a patient ***at all*** – i.e., to even a small or insignificant extent or if the degradation would take place beyond 180 days." (Report at 18)

6. Alternatively, Integra contends its "evidence presents a material issue of fact for a jury to decide regarding whether the amide linkages in the hydrogels formed with the Accused

Products are actually biodegradable while still in the patient's body as a hydrogel." (Objs. at 10) Specifically, Integra asserts it offered evidence "demonstrating that the amide linkages did not degrade '***at all***' under conditions of the accused infringing activity." (*Id.* at 8) However, the evidence Integra points to is based on its experts' improper interpretation of the claims. Rather than determining whether the linkages are biodegradable at all, Integra's experts focus on whether the amide linkages are biodegradable within a specific timeframe. (*See e.g.,* D.I. 443 at 6) This is not the correct inquiry. As the Report found, Integra's experts nowhere "opine that the amide linkages would ***never*** degrade." (Report at 21) In light of the substantial evidence Judge Burke properly analyzed, including the specifications and prosecution history of other asserted patents in the same family as the '5705 patent, the parties' experts' opinions, and references cited in the asserted patents or "otherwise in the field" (*see* Report at 11-15), which all supported a finding that the amide linkages are biodegradable, the Court agrees that there is no genuine dispute of fact that the amide linkages in the Accused Products are biodegradable.

7. The Court has considered each of the other arguments raised by Plaintiffs in their Objections *de novo* and finds that each of them lacks merit and requires no further discussion.

April 6, 2018
Wilmington, Delaware

HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE